ACCURATUS —LAB SERVICES— THE ANTIMICROBIAL AUTHORITY

AMENDMENT TO GLP TEST PROTOCOL

Amendment No.:	1
Effective Date:	July 19, 2016
Sponsor:	Virox Technologies Inc. 2770 Coventry Road Oakville, ON L6H 6R1 Canada
Test Facility:	Accuratus Lab Services 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121
Protocol Title:	Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces
Protocol Number:	VIR07052716.CHLP
Project Number:	A21262

Modifications to Protocol:

Per Sponsor request, this protocol is amended to change the source of the bottles used in testing. The spray nozzles are provided by the Sponsor and general purpose bottles are provided by Accuratus Lab Services.

Changes to the protocol are acceptable as noted.

Mary J. Mullen
Study Director

7-19-16
Date

EXACT COPY
INITIALS MM DATE 10-5-16

(For Laboratory Use Only) A21262
Accuratus Lab Services Project # V3P 7-8-16
Test Substance Tracking # TS061716. VIR07
KSH 6-22-16
and TS063016. VIR07mm7-19-16

ACCURATUS LAB SERVICES

PROTOCOL

Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

Organism: Chlamydia psittaci

PROTOCOL NUMBER

VIR07052716.CHLP

PREPARED FOR

Virox Technologies Inc.
2770 Coventry Road
Oakville, ON L6H 6R1
Canada

PERFORMING LABORATORY

Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

DATE

May 27, 2016

EXACT COPY
INITIALS MM DATE 10-5-16

Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces

SPONSOR: Virox Technologies Inc.
2770 Coventry Road
Oakville, ON L6H 6R1
Canada

TEST FACILITY: Accuratus Lab Services
1285 Corporate Center Drive, Suite 110
Eagan, MN 55121

PURPOSE
The purpose of this study is to evaluate the efficacy of a test substance against Chlamydia psittaci. The test procedure is to simulate the way in which the product is intended to be used. This method is in compliance with the requirements of and may be submitted to, one or more of the following agencies as indicated by the Sponsor: U.S. Environmental Protection Agency (EPA), Health Canada and Australian Therapeutic Goods Administration (TGA).

TEST SUBSTANCE CHARACTERIZATION
According to (40 CFR, Part 160, Subpart F [160.105]) test substance characterization as to identity, strength, purity, solubility and composition, as applicable, shall be documented before its use in this study. The stability of the test substance shall be determined prior to or concurrently with this study. Pertinent information, which may affect the outcome of this study, shall be communicated in writing to the Study Director upon sample submission to Accuratus Lab Services. Accuratus Lab Services will append Sponsor-provided Certificates of Analysis (C of A) to this study report, if requested and supplied. Characterization and stability studies not performed following GLP regulations will be noted in the Good Laboratory Practice compliance statement.

SCHEDULING AND DISCLAIMER OF WARRANTY
Experimental start dates are generally scheduled on a first-come/first-serve basis once Accuratus Lab Services receives the Sponsor approved/completed protocol, signed fee schedule and corresponding test substance(s). Based on all required materials being received at this time, the proposed experimental start date is June 20, 2016. Verbal results may be given upon completion of the study with a written report to follow on the proposed completion date of July 18, 2016. To expedite scheduling, please be sure all required paperwork and test substance documentation is complete/accurate upon arrival at Accuratus Lab Services.

If a test must be repeated, or a portion of it, because of failure by Accuratus Lab Services to adhere to specified procedures, it will be repeated free of charge. If a test must be repeated, or a portion of it, due to failure of internal controls, it will be repeated free of charge. "Methods Development" fees shall be assessed, however, if the test substance and/or test system require modifications due to complexity and difficulty of testing.

If the Sponsor requests a repeat test, they will be charged for an additional test.

Neither the name of Accuratus Lab Services nor any of its employees are to be used in advertising or other promotion without written consent from Accuratus Lab Services.

The Sponsor is responsible for any rejection of the final report by regulatory agencies concerning report format, pagination, etc. To prevent rejection, Sponsor should carefully review the Accuratus Lab Services final report and notify Accuratus Lab Services of any perceived deficiencies in these areas before submission of the report to the regulatory agency. Accuratus Lab Services will make reasonable changes deemed necessary by the Sponsor, without altering the technical data.

JUSTIFICATION FOR SELECTION OF THE TEST SYSTEM

Regulatory agencies require that a specific chlamydiacidal claim for a disinfectant intended for use on hard surfaces be supported by appropriate scientific data demonstrating the efficacy of the test substance against the claimed organism. The agency will accept adequate data generated by any appropriate technique in support of an efficacy claim. This is accomplished by treating the target organism with the disinfectant (test substance) under conditions, which simulate as closely as possible, in the laboratory, the actual conditions under which the disinfectant is designed to be used. For disinfectant products intended for use on hard surfaces (dry, inanimate environmental surfaces), a carrier method is used in the generation of the supporting data. The McCoy cell line, which supports the growth of the Chlamydia psittaci, will be used in this study. The experimental design in this protocol meets these requirements.

TEST PRINCIPLE

A film of chlamydia, dried on a glass surface, is exposed to the test substance for a specified contact time. After exposure, the chlamydiacidal and cytotoxic activities are removed from the chlamydia-test substance mixture, and the mixture is assayed for chlamydial infectivity by an accepted assay method. Appropriate chlamydia, test substance cytotoxicity, and neutralization controls are run concurrently.

STUDY DESIGN

Dried chlamydia films will be prepared in parallel and used as follows:

The appropriate number of films for each batch of test substance assayed per exposure time requested.

The appropriate number of films for chlamydia control titration (titer of chlamydia after drying) per exposure time requested.

At the end of the specified exposure time, resuspended chlamydia-test substance mixtures will be detoxified and made non-chlamydiacidal by immediately adding the contents to a Sephadex gel filtration column followed by 10-fold serial dilutions in test medium. Each dilution is inoculated into indicator cell cultures. The resuspended chlamydia control film and each batch of test substance alone will be treated in exactly the same manner. For analysis of infectivity, cultures will be held for the appropriate incubation period at the end of which time cultures will be scored for the presence of the test chlamydia. Cultures will be monitored at that time for cell viability. Uninfected indicator cell cultures will be carried in parallel and similarly monitored. For analysis of cytotoxicity, the viability of cultures inoculated with dilutions of each test and cytotoxicity control will be determined. In addition to the above titrations for infectivity and cytotoxicity, the residual chlamydiacidal activity of the test substance after neutralization will be determined by adding a low titer of chlamydia to each dilution of the test substance (cytotoxicity control dilutions). The resulting mixtures of dilutions are assayed for infectivity in order to determine the dilution(s) of test substance at which chlamydiacidal activity, if any, is retained.

CHLAMYDIA

The 6 BC strain of Chlamydia psittaci to be used for this study was obtained from the American Type Culture Collection, Manassas, VA (ATCC VR-125). The chlamydia is prepared by standard techniques, and the high titer chlamydia may be stored at ≤ -70°C until the day of use. On the day of use, an aliquot is removed, thawed and maintained at a refrigerated temperature until used in the assay. **Note:** If the Sponsor requests an organic soil load challenge, fetal bovine serum (FBS) or the requested organic soil will be incorporated into the stock chlamydia aliquot. The stock chlamydia aliquot will be adjusted to yield the percent organic soil load requested.

INDICATOR CELL CULTURES

Cultures of McCoy cells were originally obtained from the American Type Culture Collection, Manassas, VA (ATCC CRL-1696). The cells are propagated by Accuratus Lab Services personnel. The cells are seeded into multiwell cell culture plates and maintained at 36-38°C in a humidified atmosphere of 5-7% CO_2. The confluency of the cells will be appropriate for the test chlamydia. McCoy cells obtained from an alternate, reputable source may be used. The source of the cells will be specified in the final report.

All cell culture documentation is retained for the cell cultures used in this assay with respect to source, passage number, growth characteristics, seeding densities and the general condition of the cells.

TEST MEDIUM

The test medium used for this assay is Minimum Essential Medium (MEM) supplemented with 10% (v/v) heat inactivated fetal bovine serum. The medium may also be supplemented with one or more of the following: 10 µg/mL gentamicin, 2.5 µg/mL amphotericin B, 4.5 g/L glucose, 2 µg/mL cycloheximide, 10 mM HEPES. The composition of the test medium may be altered based on the chlamydia and/or cells. The composition of the medium will be specified in the final report.

PREPARATION OF TEST SUBSTANCE

The dilution of test substance(s) will be used as recommended by the Sponsor. The product will be pre-equilibrated to the desired test temperature if applicable.

PREPARATION OF CHLAMYDIA FILMS

Films of chlamydia will be prepared by spreading 200 µL of chlamydia inoculum uniformly over the bottom of the appropriate number of 100 X 15 mm sterile glass petri dishes (without touching the sides of the petri dish). The films will be air-dried at 10°C-30°C until visibly dry (≥20 minutes). A calibrated timer will be used for timing the drying. The drying conditions (temperature and humidity) will be appropriate for the test chlamydia for the purpose of obtaining maximum survival following drying. The actual drying conditions, drying time and calibrated timer used will be clearly documented.

One dried chlamydia film per batch of test substance will be assayed unless otherwise requested.

TEST METHOD

Preparation of Sephadex Gel Filtration Columns

To reduce the cytotoxic level of the chlamydia-test substance mixture prior to assay of chlamydia, and/or to reduce the chlamydiacidal level of the test substance, chlamydia is separated from the test substance by filtration through Sephadex gel. The type of Sephadex used will be specified in the final report. On the day of testing, Sephadex columns are prepared by centrifuging the prepared Sephadex gel in sterile syringes for three minutes to clear the void volume. The columns are now ready to be used in the assay.

Input Chlamydia Control

On the day of testing, the stock chlamydia utilized in the assay will be titered by 10-fold serial dilution and assayed for infectivity to determine the starting titer of the chlamydia. The results of this control are for informational purposes only.

Treatment of Chlamydia Films with the Test substance
For each batch of test substance assayed, the appropriate number of dried chlamydia films are individually exposed to a 2.0 mL aliquot of the use dilution of the test substance (liquid products), or to the amount of spray released under use conditions (spray products) and held covered for the specified exposure time(s) and temperature. A calibrated timer will be used for timing the exposure. The actual temperature will be recorded. Just prior to the end of the exposure time, the plates are individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the chlamydia-test substance mixtures are immediately passed through individual Sephadex columns utilizing the syringe plunger in order to detoxify the mixture. The filtrate (10^{-1} dilution) is then titered by serial dilution and assayed for infectivity and/or cytotoxicity. To further aid in the removing of the cytotoxic effects of the test substance to the indicator cell cultures, individual dilutions may be passed through additional individual Sephadex columns.

Treatment of Dried Chlamydia Control Film
The appropriate number of chlamydia films are prepared as described previously for each exposure time assayed. The chlamydia control films are run in parallel to the test chlamydia but a 2.0 mL aliquot of test medium is added in lieu of the test substance. The chlamydia control films are held covered and exposed to the test medium for the same exposure time and at the same exposure temperature as the test films are exposed to the test substance. A calibrated timer will be used for timing the exposure and the actual temperature will be recorded. Just prior to the end of the exposure time, the chlamydia films are individually scraped as previously described and at the end of the exposure time the mixtures are immediately passed through individual Sephadex columns utilizing the syringe plunger. The filtrate (10^{-1} dilution) is then titered by serial dilution and assayed for infectivity. If additional Sephadex columns were used to further reduce the cytotoxic effects in the test substance assay, the same dilutions of the chlamydia control will be passed through additional individual Sephadex columns.

Cytotoxicity Control
A 2.0 mL aliquot of each batch of test substance (liquid products) or the amount of the test substance recovered when sprayed onto a sterile petri dish (spray products), is filtered through a Sephadex column utilizing the syringe plunger and the filtrate is diluted serially in medium and inoculated into cell cultures for assay of cytotoxicity concurrently with the chlamydia control and test substance-treated chlamydia samples. For spray products, the cytotoxicity control will be held covered for the longest requested exposure time at the requested exposure temperature. A calibrated timer will be used for timing the exposure. If additional Sephadex columns were used to further reduce the cytotoxic effects in the test substance assay, the same dilutions of the cytotoxicity control will be passed through additional individual Sephadex columns.

Assay of Non-Chlamydiacidal Level of Test Substance (Neutralization Control)
Each dilution of the neutralized test substance (cytotoxicity control dilutions) will be challenged with an aliquot of low titer stock chlamydia to determine the dilution(s) of test substance at which chlamydiacidal activity, if any, is retained. Dilutions that show chlamydiacidal activity will not be considered in determining reduction of the chlamydia by the test substance.

Using the cytotoxicity control dilutions prepared above, an additional set of indicator cell cultures will be inoculated with a 200 µL aliquot of each dilution in quadruplicate. A 200 µL aliquot of low titer stock chlamydia will be inoculated into each cell culture well and the indicator cell cultures will be incubated along with the test and chlamydia control plates.

Infectivity Assays
The McCoy cell line, will be utilized in the infectivity assays. Cells in 24 well disposable tissue culture plates will be inoculated with 200 µL of the dilutions prepared from the test and control groups. The input chlamydia control will be inoculated in duplicate. Uninfected indicator cell cultures (cell controls) will be inoculated with test medium alone. The inoculum is allowed to adsorb for a minimum of 90 minutes at 36-38°C in a humidified atmosphere of 5-7% CO_2. Following the adsorption period, a 1.0 mL aliquot of test medium is added to each well. The cultures are incubated for approximately 2-3 days at 36-38°C in a humidified atmosphere of 5-7% CO_2. All cultures are observed microscopically for cytotoxicity followed by a fluorescent antibody assay. The fluorescent antibody assay utilizes fluorescein conjugated monoclonal antibodies for the detection of the genus *Chlamydia*.

DATA ANALYSIS

Calculation of Titers
Chlamydial and cytotoxicity titers will be expressed as $-\log_{10}$ of the 50 percent titration endpoint for infectivity ($TCID_{50}$) or cytotoxicity (TCD_{50}), respectively, as calculated by the method of Spearman Karber.

$$-\text{Log of 1st dilution inoculated} - \left[\left(\left(\frac{\text{Sum of \% mortality at each dilution}}{100}\right) - 0.5\right) \times (\text{logarithm of dilution})\right]$$

Calculation of Log Reduction

Dried Chlamydia Control Log_{10} $TCID_{50}$ – Test Substance Log_{10} $TCID_{50}$ = Log Reduction

If multiple dried chlamydia control replicates are performed, the average titer of the replicates will be calculated and the average titer will be used to calculate the log reduction in chlamydial titer of the individual test replicates.

PROCEDURE FOR IDENTIFICATION OF THE TEST SYSTEM

The specialized virucidal testing section of Accuratus Lab Services maintains Standard Operating Procedures (SOPs) relative to chlamydiacidal efficacy testing studies. Chlamydiacidal efficacy testing is performed in strict adherence to these SOPs which have been constructed to cover all aspects of the work including, but not limited to, receipt, log-in, and tracking of biological reagents including chlamydia and cell stocks for purposes of identification, receipt and use of chemical reagents including cell culture medium components, etc. These procedures are designed to document each step of chlamydiacidal efficacy testing studies. Appropriate references to medium, batch number, etc. are documented in the raw data collected during the course of each study.

Additionally, each chlamydiacidal efficacy test is assigned a unique Project Number when the Study Director initiates the protocol for the study. This number is used for identification of the test culture plates, etc. during the course of the test. Test culture plates are also labeled with reference to the test chlamydia, experimental start date, and test product. These measures are designed to document the identity of the test system.

METHOD FOR CONTROL OF BIAS: N/A

STUDY ACCEPTANCE CRITERIA

Only the applicable acceptance criteria and references for the regulatory agency reviewing the data will be included in the final report.

U.S. EPA, Health Canada, and Australian TGA Submission
A valid test requires 1) that at least 4 $\log_{10}$ of infectivity be recovered from the dried chlamydia control film; 2) that when cytotoxicity is evident, at least a 3-log reduction in titer is demonstrated beyond the cytotoxic level; 3) that the cell controls be negative for infectivity. If any of the previous requirements are not met, the test may be repeated under the current protocol number. **Note:** An efficacious product must demonstrate complete inactivation of the chlamydia at all dilutions.

FINAL REPORT
The report will include, but not be limited to, identification of the sample and date received, dates on which the test was initiated and completed, identification of the chlamydia strain used and composition of the inoculum, description of cells, medium and reagents, description of the methods employed, tabulated results, calculated titers for infectivity and cytotoxicity, and a conclusion as it relates to the purpose of the test. A draft report may be requested by the Sponsor. The final report will be prepared once the Sponsor has reviewed the draft report and notified the Study Director to complete the study.

PROTOCOL CHANGES
If it becomes necessary to make changes in the approved protocol, the revision and reasons for change will be documented, reported to the Sponsor and will become a part of the permanent file for that study. Similarly, the Sponsor will be notified as soon as possible whenever an event occurs that may have an effect on the validity of the study.

TEST SUBSTANCE RETENTION
Test substance retention shall be the responsibility of the Sponsor. Unused test substance will be **discarded** following study completion unless otherwise requested.

RECORD RETENTION

Study Specific Documents

All of the original raw data developed exclusively for this study shall be archived at Accuratus Lab Services for a minimum of five years for GLP studies or a minimum of six months for all other studies following the study completion date. After this time, the Sponsor (or the Sponsor Representative, if applicable) will be contacted to determine the final disposition. These original data include, but are not limited to, the following:

1. All handwritten raw data for control and test substances including, but not limited to, notebooks data forms and calculations.
2. Any protocol amendments/deviation notifications.
3. All measured data used in formulating the final report.
4. Memoranda, specifications, and other study specific correspondence relating to interpretation and evaluation of data, other than those documents contained in the final study report.
5. Original signed protocol.
6. Certified copy of the final study report.
7. Study-specific SOP deviations made during the study.

Facility Specific Documents

The following records shall also be archived at Accuratus Lab Services. These documents include, but are not limited to, the following:

1. SOPs, which pertain to the study, conducted.
2. Non study-specific SOP deviations made during the course of this study, which may affect the results, obtained during this study.
3. Methods which were used or referenced in the study conducted.
4. QA reports for each QA inspection with comments.
5. Facility Records: Temperature Logs (ambient, incubator, etc.), Instrument Logs, Calibration and Maintenance Records.
6. Current curriculum vitae, training records, and job descriptions for all personnel involved in the study.

PROPOSED STATISTICAL METHODS: N/A

REFERENCES

1. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides, Antimicrobials, and Alternative Control Agents; Environmental Assessment; Hazardous Substances and Oil Spill Response, E1053-11.
2. Annual Book of ASTM Standards, Section 11 Water and Environmental Technology Volume 11.05 Pesticides, Antimicrobials, and Alternative Control Agents; Environmental Assessment; Hazardous Substances and Oil Spill Response, E1482-12.
3. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2000: General Considerations for Uses of Antimicrobial Agents, September 4, 2012.
4. U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention, Product Performance Test Guidelines, OCSPP 810.2200: Disinfectants for Use on Hard Surfaces – Efficacy Data Recommendations, September 4, 2012.
5. Diagnostic Procedures for Viral, Rickettsial, and Chlamydial Infections. Lennette, E.H., Lennette, D.A. and Lennette, E.T. editors. Seventh edition, 1995.
6. Blackwell, J.H., and J.H.S. Chen. 1970. Effects of various germicidal chemicals on HEP-2 cell culture and Herpes simplex virus. J. AOAC 53:1229-1236.
7. Health Canada, January, 2014. Guidance Document - Disinfectant Drugs.
8. Health Canada, January, 2014. Guidance Document - Safety and Efficacy Requirements for Hard Surface Disinfectant Drugs.
9. Australian Therapeutic Goods Administration (TGA), February 1998. Guidelines for the Evaluation of Sterilants and Disinfectants.
10. Australian Therapeutic Goods Administration (TGA), February 1998. Therapeutic Goods Order No. 54: Standard for Disinfectants and Sterilants.
11. Australian Therapeutic Goods Administration (TGA), March 1997. Therapeutic Goods Order No. 54A: Amendment to Standard for Disinfectants and Sterilants (TGO 54).
12. Australian Therapeutic Goods Administration (TGA), July 2005. Draft Guidelines for the Evaluation of Household/Commercial and Hospital Grade Disinfectants.

STUDY INFORMATION

(All blank sections are completed by the Sponsor or Sponsor Representative as linked to their signature, unless otherwise noted.)

Test Substance (Name and lot number - exactly as should appear on final report)

OXYTEAM

LOT # 12298, 12299

Testing at the lower certified limit (LCL) for the hardest-to-kill virus on your label is required for registration.

Product Description

☐ Quaternary ammonia ☐ Peracetic acid ☐ Sodium hypochlorite
☐ Iodophor ☑ Peroxide ☐ Other_____

Approximate Test Substance Active Concentration (upon submission to Accuratus Lab Services): Lot # 12298: 4.04% Lot # 12299: 4.04%

(This value is used for neutralization planning only. This value is not intended to represent characterization values.)

Storage Conditions

☑ Room Temperature ☐ 2-8°C ☐ Other_____

Hazards

☐ None known: Use Standard Precautions
☑ Material Safety Data Sheet, Attached for each product
☐ As Follows: _____

Product Preparation

☐ No dilution required, Use as received (RTU)
☑ *Dilution(s) to be tested:
1:64 (example: 1 oz/gallon) defined as 2 Oz (amount of test substance) + 1 Gallon of water (amount of diluent)
☐ Deionized Water (Filter or Autoclave Sterilized)
☐ Tap Water (Filter or Autoclave Sterilized)
☑ AOAC Synthetic Hard Water: 200 PPM
☐ Other _____

*Note: *An equivalent dilution may be made unless otherwise requested by the Sponsor.*

Test Chlamydia: Chlamydia psittaci

Exposure Time: 5 min.

Exposure Temperature: ☑ Room temperature (to be based on regulatory agency of submission)
☐ Other:_____°C (please specify range)

Directions for application of aerosol/spray products:

☐ Spray instructions are not applicable.

Trigger spray application:

☑ Spray carriers using 3 sprays, or until thoroughly wet, at a distance of 6 to 8 inches.
☐ Spray carriers using _____ sprays at a distance of _____ to ____ inches/cm. (circle one)

Aerosol spray application:

☐ Spray carriers for _____ seconds, or until thoroughly wet, at a distance of _____ to ____ inches/cm.

Note: Per 6-29-16 email, Sponsor would like their trigger spray bottles used in testing. mm 6-29-16

Organic Soil Load
- ☐ 1% fetal bovine serum (minimum level that can be tested)
- ☑ 5% fetal bovine serum
- ☐ Other_____

REGULATORY AGENCY(S) THAT MAY REVIEW DATA
- ☑ U.S. EPA
- ☐ Health Canada
- ☐ Therapeutic Goods Administration (Australian TGA)
- ☐ Not applicable - For internal/other use only (Efficacy result will be based on U.S. EPA requirements)

PROTOCOL MODIFICATIONS
- ☑ Approved without modification
- ☐ Approved with modification

PROTOCOL ATTACHMENTS
Supplemental Information Form Attached - ☐ Yes ☑ No

TEST SUBSTANCE SHIPMENT STATUS
(This section is for informational purposes only.)
- ☐ Test Substance is already present at Accuratus Lab Services.
- ☑ Test Substance has been or will be shipped to Accuratus Lab Services.
  Date of expected receipt at Accuratus Lab Services: Received 10-17-16 MM 6-7-16
- ☐ Test Substance to be hand-delivered (must arrive by noon at least one day prior to testing or other arrangements made with the Study director)

COMPLIANCE
Study to be performed under EPA Good Laboratory Practice regulations (40 CFR Part 160) and in accordance to standard operating procedures.
☑ Yes
☐ No (Non-GLP or Development Study)

TEST SUBSTANCE CHARACTERIZATION & STABILITY TESTING
[Verification required per 40 CFR Part 160 Subpart B (160.31(d))].

☐ Characterization/Stability testing is not required (For Non-GLP or Development testing only)

OR

Physical and Chemical Characterization (identity, purity, strength, solubility, as applicable) of the test lots

☑ Physical & Chemical Characterization has been or will be completed prior to efficacy testing.

GLP compliance status of physical & chemical characterization testing:
☑ Testing was or will be performed following 40 CFR Part 160 GLP regulations
☐ Characterization has not been or will not be performed following GLP regulations

Check and complete the following that apply:
☑ A Certificate of Analysis (C of A) has been or will be provided for each lot of test substance to be appended to the report.
☐ Testing has been or will be conducted at Accuratus Lab Services under protocol or study #:

_____

☐ Test has been or will be conducted by another facility under protocol or study #:

_____

☐ Physical & Chemical Characterization was not or will not be performed prior to efficacy testing.

Stability Testing of the formulation

☑ Stability testing has been or will be completed prior to or concurrent with efficacy testing.

GLP compliance status of stability testing:
(GLP compliance is required by 40 CFR Part 160)
☑ Testing was or will be performed following 40 CFR Part 160 GLP regulations
☐ Stability testing has not been or will not be performed following GLP regulations

Check and complete the following that apply:
☐ Testing has been or will be conducted at Accuratus Lab Services under protocol or study #:

_____

☑ Test has been or will be conducted by another facility under protocol or study #:
STUDY NO. 1029RA1

☐ Stability testing was not or will not be performed prior to or concurrent with efficacy testing.

If test substance characterization or stability testing information is not provided or is not performed following GLP regulations, this will be indicated in the GLP compliance statement of the final report.

APPROVAL SIGNATURES

SPONSOR:

NAME: Mr. Babak Givehchi TITLE: Senior Vice President of Quality Assurance and Regulatory Affairs

SIGNATURE: [signature] DATE: 06/10/16

PHONE: 1 (905) 813 - 0110 FAX: _____ EMAIL: babak@virox.com

For confidentiality purposes, study information will be released only to the sponsor/representative signing the protocol (above) unless other individuals are specifically authorized in writing to receive study information.

Other individuals authorized to receive information regarding this study: ☐ See Attached

Lok Chum, Faraz Ahmadpour

Accuratus Lab Services:

NAME: Mary J. Miller
Study Director

SIGNATURE: Mary J. Miller
Study Director DATE: 6-29-16